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k022255
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3. **510(k) Summary:**

510(k) SUMMARY

Submitter:	Synthes (USA) 1690 Russell Road Paoli, PA 19301
Company Contact:	Matthew M. Hull (610) 647-9700
Name of the Device:	Synthes (USA) Ankle Arthrodesis Plates
Classification:	Class II, 21 CFR 888.3030
Common or Usual Name:	Plate, Fixation, Bone, Non-spinal
Predicate (unmodified) Device:	Synthes Ankle Arthrodesis Plates, K013415
Device Description:	The Synthes Ankle Arthrodesis Plates are minimally contoured metal plates that utilize traditional internal plate/screw fixation to promote fusion or "arthrodesis" of the ankle.
Intended Use:	The Synthes Ankle Arthrodesis Plates are intended for arthrodesis of the ankle and the distal tibia.
Material:	Stainless Steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 5 2002

Mr. Matthew M. Hull, RAC
Senior Regulatory Affairs Specialist
Synthes (USA)
1690 Russell Road
PO Box 1766
Paoli, Pennsylvania 19301

Re: K022255
Trade/Device Name: Synthes Ankle Arthrodesis Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: July 9, 2002
Received: July 12, 2002

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

Special 510(k) Device Modification

INTENDED USE STATEMENT

510(k) Number (if known): K022255

Device Name: Synthes Ankle Arthrodesis Plates

Indications: The Synthes Ankle Arthrodesis Plates are intended for arthrodesis of the ankle joint and distal tibia.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022255